Court of Justice of European Union Clarifies Scope of Officinal Formula Exemption Under EU Medicinal Product Law

On 19 March 2026, the Court of Justice of the European Union (***CJEU***) ruled that national legislation imposing an authorisation requirement on pharmacy-compounded officinal formula medicinal products on the basis of a quantitative numerical criterion falls outside the scope of Directive 2001/83/EC of 6 November 2001 on the Community code relating to medicinal products for human use (***Directive 2001/83/EC***). The CJEU held that when a medicinal product satisfies all the conditions set out in Article 3(2) of Directive 2001/83/EC (***Article 3(2)***), it is excluded from the Directive's scope entirely, and Member States retain full competence to regulate such products under national law (CJEU, 19 March 2026, Case C-589/24, *Almirall*, EU:C:2026:217; the ***Judgment***, available here).

Article 3(2) excludes from the scope of application of Directive 2001/83/EC "[a]*ny medicinal product which is prepared in a pharmacy in accordance with the prescriptions of a pharmacopoeia and is intended to be supplied directly to the patients served by the pharmacy in question (commonly known as the officinal formula)*".

Background and facts of case

The case involves Almirall BV and Almirall SA (together, ***Almirall***), an international pharmaceutical company which produces and sells the medicinal product Skilarence®, which is indicated for the treatment of psoriasis. Skilarence®, whose active substance is dimethyl fumarate, has been available on the Netherlands market since 1 July 2008 under marketing and manufacturing authorisations issued in accordance with Dutch law implementing Directive 2001/83/EC.

Two dispensing pharmacies, Infinity Pharma BV and its sister company Pharmaline BV (***Pharmaline***), prepared and supplied a competing product, Psorinovo®, containing the same active substance, for the treatment of psoriasis. Unlike Skilarence®, an authorised medicinal product, Psorinovo® was prepared in the pharmacies' own premises in accordance with pharmacopoeia prescriptions and supplied directly to the pharmacies' patients, without marketing or manufacturing authorisations. In April 2019, the Dutch Minister for Medical Care and Sport indicated in a letter to Parliament that pharmacy-prepared medicinal products are exempt from authorisation requirements on the condition that they are prepared in small quantities, a condition operationalised as a numerical criterion of no more than 50 different patients per month in the case of long-term use.

Almirall brought civil proceedings before various Dutch courts seeking injunctions against both pharmacies, arguing that their preparation and supply of Psorinovo® exceeded the numerical criterion and therefore required marketing and manufacturing authorisations. The lower courts upheld Almirall's claim and imposed cease-and-desist orders on both pharmacies. On appeal, however, the Court of Appeal of Arnhem-Leeuwarden (*Gerechtshof Arnhem-Leeuwarden*) held that Pharmaline's preparation of Psorinovo® satisfied the conditions of Article 3(2) and that that provision imposed no quantitative condition, with the result that the numerical criterion could not be applied to products qualifying as officinal formulas. Almirall subsequently appealed on a point of law to the Supreme Court of the Netherlands (*Hoge Raad der Nederlanden*), which stayed the proceedings and referred four preliminary questions to the CJEU, asking, in essence:

(i) whether a Directive-compliant interpretation of Dutch law, in the light of Article 3(2), allows national authorisation exceptions to be assessed on the basis of a quantitative numerical criterion;

(ii) whether national authorities are free to subject a medicinal product falling under Article 3(2) to a national authorisation requirement based on a quantitative criterion;

(iii) whether the level of harmonisation effected by Directive 2001/83/EC is relevant to the answers to the preceding questions; and

(iv) whether the Dutch-language version of the second subparagraph of Article 40(2) of Directive 2001/83/EC on the manufacturing authorisation, which refers to supply "*in het klein*" ("retail supply"), is relevant to the interpretation of Article 3(2).

Reasoning of CJEU

The CJEU examined all four questions together. It began by setting out the relationship between Articles 2(1) and 3 of Directive 2001/83/EC. Article 2(1) defines the Directive's positive scope, covering medicinal products prepared industrially or manufactured by a method involving an industrial process, while Article 3 carves out specific exclusions from that scope. A product must therefore both satisfy the conditions of Article 2(1) and fall outside the exclusions in Article 3 in order to come within the Directive's scope (*see*, CJEU, 26 October 2016, Case C-276/15, *Hecht-Pharma*, EU:C:2016:801, available here, and CJEU, 21 November 2018, Case C-29/17, *Novartis Farma*, EU:C:2018:931, available here).

Turning to Article 3(2), the CJEU confirmed that the officinal formula exemption applies to any medicinal product that is: (i) prepared in a pharmacy; (ii) in accordance with the prescriptions of a pharmacopoeia; and (iii) intended to be supplied directly to the patients served by that pharmacy. While the three conditions are cumulative, they are also exhaustive. The application of Article 3(2) requires only that the conditions expressly laid down in that provision be met (*see*, CJEU, Joined Cases C-544/13 and C-545/13, *Abcur*, EU:C:2015:481, available here).

Consequently, the CJEU held that, if all three conditions of Article 3(2) are satisfied, the medicinal product in question falls entirely outside the scope of Directive 2001/83/EC (Judgment, §39). As a result, any national legislation imposing authorisation requirements on such products, including requirements based on quantitative numerical criteria, does not come within the scope of the Directive and falls instead within the competences retained by Member States. Such legislation is not subject to the requirements or constraints of Directive 2001/83/EC and does not have to be interpreted in conformity with it (Judgment, §40).

On the question of the level of harmonisation effected by Directive 2001/83/EC, the CJEU held that this was irrelevant. Whether the Directive provides for full or minimum harmonisation has no effect on the margin of discretion available to Member States when regulating medicinal products covered by Article 3(2), precisely because such products are outside the Directive's scope altogether (Judgment, §41).

On the fourth question, the CJEU held that the expression "retail supply" in the second subparagraph of Article 40(2) of Directive 2001/83/EC, and its Dutch-language rendering as supply "*in het klein*" ("in small quantities" or "retail supply"), is irrelevant to the interpretation of Article 3(2). The two provisions serve different purposes: while Article 3(2) defines the Directive's scope, the second subparagraph of Article 40(2)

concerns the conditions under which certain manufacturing processes for products already within the Directive's scope are exempt from the requirement to hold a manufacturing authorisation. Since their respective objectives and fields of application differ, Article 40(2) cannot supplement or inform the conditions laid down in Article 3(2) (Judgment, §38).

Applying these principles to the facts of the case, the CJEU noted that, subject to the referring court's verification, Psorinovo® appeared to satisfy all the conditions of Article 3(2): it was prepared by dispensing pharmacies in accordance with pharmacopoeia prescriptions and supplied directly to those pharmacies' patients. The Netherlands' numerical criterion therefore fell outside the Directive's scope and was governed solely by national law (Judgment, §42).

Assessment

The CJEU provided helpful clarification on the boundaries between EU harmonisation and Member State autonomy in the regulation of pharmacy-compounded medicinal products. By confirming that the conditions of Article 3(2) are both cumulative and exhaustive, the CJEU has definitively closed the door to arguments that Member States must justify additional quantitative restrictions on officinal formula products by reference to Directive 2001/83/EC. Once a product satisfies the three conditions of Article 3(2), it leaves the EU regulatory framework entirely, and Member States may legislate freely within the space that national law provides.

This outcome has significant practical implications. On the one hand, it confirms that dispensing pharmacies which prepare and supply officinal formula products strictly in accordance with their own patient base are shielded from the marketing and manufacturing authorisation requirements imposed by Directive 2001/83/EC. On the other hand, and perhaps more consequentially, it also makes clear that any additional national restrictions on such products, including numerical limits of the kind at issue in this case, are matters of national law alone, with no duty on national courts to interpret them in conformity with the Directive. This places questions of access to compounded medicines, competitive balance between pharmacies and industrial manufacturers (read: pharmaceutical companies), and public health oversight squarely within the domain of national regulatory policy.

The “industrial” preparation/manufacturing criterion of Article 2(1) of Directive 2001/83/EC does not feature in the current draft Directive “on the Union code relating to medicinal products for human use” as proposed as part of the pharmaceutical package to replace Directive 2001/83/EC (*see*, *Van Bael & Bellis Life Sciences News & Insights* of 6 March 2026). However, the draft Directive still excludes from its scope “*medicinal products prepared in a pharmacy in accordance with a pharmacopoeia and intended to be supplied directly to the patients served by the pharmacy in question (‘officinal formula’)*” (Article 1(5(b)). The latter exclusion does not apply to (i) advanced therapy medicinal products (to which the “hospital exemption” could apply – *see*, Article 3 of the draft Directive); and (ii) medicinal products developed by means of one of the following biotechnological processes: (a) recombinant nucleic acid technology; or (b) controlled expression of genes coding for biologically active proteins in prokaryotes and eukaryotes including transformed mammalian cells.

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Van Bael & Bellis